**IN THE UNITED STATES DISTRICT COURT**
**FOR THE WESTERN DISTRICT OF TEXAS**
**AUSTIN DIVISION**

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| **THE STATE OF TEXAS, *ex. rel.* ALLISON ZAYAS and TRACY MIKSELL-BRANCH,** | § | |
| **Plaintiffs,** | § | |
| | § | NO.: _____ |
| **v.** | § | |
| **ASTRAZENECA, L.P., and ASTRAZENECA PHARMACEUTICALS, L.P.,** | § | |
| **Defendants.** | § | |

**NOTICE OF REMOVAL**

Defendants AstraZeneca, L.P. and AstraZeneca Pharmaceuticals, L.P., (collectively "AstraZeneca" or "Defendants"), provide notice pursuant to 28 U.S.C. § 1446 of the removal of the above-captioned case from the 353rd District Court for Travis County, Texas to the United States District Court for the Western District of Texas. This Court has subject matter jurisdiction under 28 U.S.C. § 1331 because plaintiffs' Second Amended Petition ("Petition") raises substantial and disputed federal issues, *see, e.g.*, *Grable & Sons Metal Prods., Inc. v. Darue Eng'g & Mfg.*, 545 U.S. 308 (2005), and the matter is thus removable pursuant to 28 U.S.C. §§ 1441 and 1446.

One of the Relators in this action filed a lawsuit in the United States District Court for the District of Delaware, alleging substantially the same claims against AstraZeneca as those alleged by Texas here. *See United States of America ex rel. Tracy Miksell-Branch et al v. AstraZeneca Pharmaceuticals L.P. et al*, 1:10-cv-00154-SLR at

D.I. 51.[1] Texas was a party to that lawsuit, but voluntarily dismissed the claims so it could pursue this action instead. *Id.* at D.I. 43. However, the related Delaware matter is ongoing.

As explained below, while plaintiffs purport to assert only state law claims, the validity of those claims is predicated on the complex federal scheme governing the labeling and marketing of prescription drugs and the coverage and reimbursement for prescription drugs under Medicaid. Indeed, the Petition describes the federal "FDA Regulatory System" in detail (*see* Pet. ¶¶ 26-38), including the core allegations that (a) a "drug's sponsor is legally [] authorized to promote" a prescription drug for uses approved by the FDA (*id.* ¶ 29), and (b) the federal Food, Drug and Cosmetics Act ("FDCA") prohibits "misbranding" of prescription drugs. *Id.* ¶¶ 30-35. Similarly the Petition describes the federal statutory scheme which dictates whether and when a prescription drug is subject to reimbursement by Medicaid. *See id.* ¶¶ 42-47. Plaintiffs' purported state law claims rest entirely on the theory that, through various allegedly false and misleading actions, AstraZeneca misbranded Seroquel IR and Seroquel XR in violation of the FDCA. *See id.* ¶¶ 75, 82, 92, 104, 108, 116. Whether AstraZeneca engaged in misbranding will necessarily be decided under federal law.[2]

Plaintiffs' claims therefore necessarily depend upon the resolution of disputed and substantial questions of federal law over which federal courts have original jurisdiction. *See Grable*, 545 U.S. at 314. In addition to pleading specific violations of federal law,

[1] References to "D.I." correlate to the docket entries for *United States of America ex rel. Tracy Miksell-Branch v. AstraZeneca Pharmaceuticals L.P.*, 1:10-cv-00154-SLR (D. Del.).

[2] While plaintiffs also allege that AstraZeneca misbranded Seroquel in violation of state law, they cite no state statute or regulation related to misbranding.

plaintiffs' Petition directly implicates the FDCA, the federal Medicaid Act, and associated federal regulations. Indeed, plaintiffs' claims require application and interpretation of federal law, including: (i) the FDCA, 21 U.S.C. § 301, *et seq*., and its implementing federal regulations, which govern the FDA's approval of prescription drugs and regulate prescription drug manufacturers' public and promotional statements, including all aspects of warnings and labeling; and (ii) federal Medicaid law, which determines which prescription medicines a State must cover under its Medicaid program and the delineated circumstances under which a State can decline to pay for such medicines, *see*, 42 U.S.C. §§ 1396r-8(d)(1)(B), (d)(4).

In accordance with 28 U.S.C. § 1446(a), AstraZeneca respectfully provides the following statement of the grounds for removal of this case:

**PROCEDURAL BACKGROUND**

1. The State of Texas, by and through the Attorney General of Texas, Greg Abbott (the "State") and Relators Tracy Miksell-Branch and Allison Zayas (the "Relators," and, together with the State, the "Plaintiffs") commenced this action by filing an Original Petition under seal in the 353rd Judicial District Court for Travis County, Texas. Plaintiffs served AstraZeneca with their Second Amended Petition ("Petition") on November 18, 2014. Plaintiffs assert claims under the Texas Medicaid Fraud Prevention Act ("TMFPA"), TEX. HUM. RES. CODE Chapter 36, and Texas common law.

2. In accordance with 28 U.S.C. § 1446(a), copies of the Petition and all process, pleadings, and orders served on or by Defendants are attached hereto as Exhibit "A," and the allegations set forth in the Petition, although not admitted, are incorporated herein as if set out in full.

3. In compliance with 28 U.S.C. § 1446(d), a copy of the Notice of Filing Notice of Removal to the United States District Court for the Western District of Texas, Austin Division that will be filed with the District Court for Travis County, Texas is attached hereto as Exhibit "B."

4. Defendants are serving plaintiffs with written and electronic notice of the removal of this action.

5. Pursuant to 28 U.S.C. § 1446(b), this Notice of Removal is timely because fewer than thirty days have elapsed since service of the Petition on each of the Defendants.

6. Venue in this district is proper because the court in which the plaintiffs filed this action, the 353rd Judicial District Court of Travis County, Texas, sits within this federal district. *See* 28 U.S.C. §§ 1441(a) and 124(d)(1).

**JURISDICTION**

7. This Court has jurisdiction over this matter pursuant to 28 U.S.C. § 1331 because plaintiffs' claims turn on federal questions "arising under" the laws of the United States. Under *Grable,* there is federal question jurisdiction over a case involving only state law claims if any of the state law claims necessarily raises a federal question "actually disputed and substantial, which a federal forum may entertain without disturbing any congressionally approved balance of federal and state judicial responsibilities." 545 U.S. at 314; *see also West Virginia v. Eli Lilly & Co.*, 476 F. Supp. 2d 230, 234 (E.D.N.Y. 2007) (holding state-law claims in pharmaceutical marketing fraud case were removable under *Grable* because claims presented a substantial and disputed federal question and federal jurisdiction was consistent with congressional intent). Federal question jurisdiction exists where "the plaintiff's right to relief

necessarily depends on resolution of a substantial question of federal law." *Franchise Tax Bd. of State of Cal. v. Constr. Laborers Vacation Trust*, 463 U.S. 1, 27-28 (1983) (emphasis added).

8. The Supreme Court made clear in *Grable* that federal question jurisdiction does *not* require a plaintiff to assert a violation of a federal statute that provides a private right of action; *Grable* requires only that the complaint raise an appropriate federal question. 545 U.S. at 315-19 (limiting the holding of *Merrell Dow Pharmaceuticals, Inc. v. Thompson*, 478 U.S. 804 (1986), to the extent that it implied that a federal cause of action was required to remove a pharmaceutical products liability case); *see also Nicodemus v. Union Pac. Corp.*, 440 F.3d 1227, 1233 (10th Cir. 2006) (explaining that, after *Grable*, it is settled that the absence of a private right of action is not fatal to the exercise of federal question jurisdiction).

9. In affirming the removal of the state law claims in *Grable*, the Court held that "a federal court ought to be able to hear claims recognized under state law that nonetheless turn on substantial questions of federal law, and thus justify the resort to the experience, solicitude and hope of uniformity that a federal forum offers on federal issues." *Id.*; *see also Broder v. Cablevision Sys. Corp.*, 418 F.3d 187, 195-96 (2d Cir. 2005) (upholding removal where state-law claim "involve[d] aspects of a complex federal regulatory scheme").

10. Consistent with *Grable*, the Fifth Circuit has held that "federal question jurisdiction exists where (1) resolving a federal issue is necessary to resolution of the state-law claim; (2) the federal issue is actually disputed; (3) the federal issue is substantial; and (4) federal jurisdiction will not disturb the balance of federal and state

judicial responsibilities." *Singh v. Duane Morris LLP*, 538 F.3d 334, 338 (5th Cir. 2008). All four of these conditions are present here, and thus removal is appropriate.

11. ***First***, the resolution of federal issues is necessary to the resolution of all but one of plaintiffs' causes of action, *i.e.*, every cause of action except for its breach of fiduciary duty claim. The theory underlying every other cause of action is that AstraZeneca "misbranded" Seroquel in violation of the FDCA – a federal law. As plaintiffs state in the Petition "[a] drug is misbranded if the labeling is false or misleading in any particular, the labeling does not contain adequate directions for use, or the manufacturer utilizes false or misleading advertisements relating to the drug." Pet. ¶ 30 (citing to 21 U.S.C. § 352(a), (f), (n)). Because of their reliance on this theory, whether AstraZeneca violated the FDCA must be determined before plaintiffs' TMFPA, common law fraud, negligent misrepresentation, monies had and received and promissory estoppel claims can be resolved.

12. Further, resolution of plaintiffs' claims will require examination not only of the FDCA, but will also require examination of regulations promulgated by the FDA pursuant to authority granted by the FDCA, *see, e.g.*, Pet. ¶¶ 32-35, and federal case law interpreting the regulations, *see, e.g.*, Pet. ¶ 31.[3] This is patently an issue of federal law involving a complex scheme of regulations, and their resolution requires the interpretation and application of the FDCA, and the associated federal regulations and federal case law interpreting it.

[3] Plaintiffs even rely on the FDA's interpretations of some of AstraZeneca's promotional materials to support Plaintiffs' conclusion that "Seroquel XR [was] misbranded in violation of federal and state law." Pet. ¶¶ 115-16.

13. Plaintiffs' misbranding claims generally take two forms. First, plaintiffs allege that AstraZeneca illegally promoted Seroquel for non-FDA-approved uses. *See, e.g.*, Pet. ¶¶ 2, 74, 75, 82, 92, 104, 116. For example, Paragraph 75 of the Petition alleges that "Defendants misleadingly promoted the Seroquel Franchise to child and adolescent psychiatrists . . . . thus creating a new intended use for Seroquel . . . caus[ing] the Seroquel Franchise to be misbranded in violation of federal and state law." Plaintiffs' misbranding claims also turn on whether Seroquel's promotional labeling and advertisements were inconsistent with the FDA-approved label. *See, e.g.*, Pet. ¶ 116. Plaintiffs rely on this theory, in part, to support their TMFPA claims. *See, e.g.*, Pet. ¶ 128-31. This same conduct is also used to support some of plaintiffs' common law claims, *i.e.*, common law fraud, negligent misrepresentation, and monies had and received. *See, e.g.*, Pet. ¶¶ 135-37, 143-46, 148-50.

14. Plaintiffs also allege that for Seroquel to be reimbursed by Texas Medicaid, AstraZeneca had to complete a certification that provided that Seroquel was "not in violation of either state or federal law." *See, e.g.*, Pet. ¶¶ 45. According to plaintiffs, because AstraZeneca misbranded Seroquel, in violation of the FDCA, these certifications were false – *i.e.*, AstraZeneca was in violation of federal law when it signed the certification. *See, e.g.*, Pet. ¶¶ 119-22. Plaintiffs rely on this theory, in part, to support their TMFPA claims. *See id.* This same conduct is also used to support some of plaintiffs' common law claims, *i.e.*, common law fraud, negligent misrepresentation, monies had and received, and promissory estoppel. *See, e.g.*, Pet. ¶¶ 135-37, 143-46, 148-50, 154-58.

15. Plaintiffs also seek to recoup the costs incurred in reimbursing Seroquel prescriptions written by licensed Texas physicians resulting, at least in part, from AstraZeneca's alleged "off-label" promotion. *See* Pet. ¶¶ 122-23, 149, 151, 160, Prayer for Relief. Plaintiffs' claims depend, as a threshold matter, upon proof that plaintiffs could have, consistent with federal law, refused to pay for the Seroquel prescriptions that plaintiffs now claim they did not "intend" to reimburse. An analysis of such claims requires the presiding court to address complex federal statutory and regulatory standards in order to determine whether plaintiffs can establish the prima facie elements of their claims.

16. The Federal Medicaid statute allows a participating state to exclude or otherwise restrict coverage of a prescription drug only in specified circumstances. One such circumstance is that a state may deny reimbursement if the prescribed use is not a "medically accepted indication," a term that is defined by federal law. *See* 42 U.S.C. § 1396r-8(k)(6); *see also* Pet. ¶ 43 (recognizing Texas is not authorized by federal law to reimburse for indications that are not "medically accepted"). The "term 'medically accepted indication' means any use for a covered outpatient drug which is approved under the Federal Food, Drug, and Cosmetic Act, or the use of which is supported by one or more citations included or approved in any one of the compendia described in" the Federal Medicaid statute. 42 U.S.C. § 1396r-8(k)(6).

17. Although the Federal Medicaid statute, by its terms, mandates reimbursement for all prescriptions for all medically accepted uses, plaintiffs' Petition posits an exception to the mandate: plaintiffs claim a right to refuse to reimburse for any uses, including FDA-approved uses and off-label but medically-accepted uses, whenever

a pharmaceutical manufacturer has engaged in off-label marketing. *See* Pet. ¶¶ 122, 123, 149, 151, 160, Prayer for Relief. Indeed, in Paragraph 160, plaintiffs allege that as a remedy for its common law causes of action it seeks "restitution for the value of ***all*** payments that the state has made for Seroquel IR and Seroquel XR prescriptions reimbursed under the Texas Medicaid Program." (emphasis added). To the extent plaintiffs are relying on their first theory of misbranding – off-label promotion by AstraZeneca – plaintiffs are seeking reimbursement for all Seroquel prescriptions regardless of whether AstraZeneca's conduct caused the prescription. The Federal Medicaid statute provides for no such exception.

18. Recovery on plaintiffs' claims regarding "misbranding," then, turns on substantial and disputed federal questions: the proper interpretation of the reimbursement provisions of the federal Medicaid statute, including whether the State is authorized by the federal Medicaid statute to refuse to reimburse for prescriptions for Seroquel, regardless of whether they are written for "medically accepted" uses (including uses "supported by one or more citations included or approved for inclusion in any one of the compendia"), as defined by federal statute. *See* 42 U.S.C. § 1396r-8(k)(6).

19. Plaintiffs cannot, by alleging only state-law claims, escape the fact that federal standards control. In order to succeed on five out of their six asserted causes of action, plaintiffs must prove that AstraZeneca's promotion of Seroquel products was in violation of the FDCA or that AstraZeneca's Seroquel products were not eligible for reimbursement under the Federal Medicaid statute. Whether plaintiffs can make this showing depends on interpretation and application of the *federal* FDCA, the *federal* Medicaid Act, and their associated *federal* regulations, plus federal case law. In other

words, "resolving a federal issue is necessary to resolution of the state-law claim[s]." *See Singh,* 538 F.3d at 338.

20. ***Second***, the core issues of federal law—whether Seroquel was improperly promoted and thus misbranded under the FDCA, its regulations and the federal case law interpreting them, and whether Seroquel was eligible for Medicaid reimbursement for the uses for which it was allegedly promoted—are disputed in this case. Among other things, AstraZeneca challenges plaintiffs' interpretation of the requirements and restrictions of the FDCA and the Medicaid Act, and their associated federal regulations. In particular, AstraZeneca disputes that Seroquel was misbranded. Additionally, AstraZeneca disputes plaintiffs' premise that plaintiffs may – without violating federal Medicaid law – refuse to pay for Seroquel prescriptions where reimbursement was consistent with the dictates of federal law.

21. ***Third***, a product's safety and efficacy, approved uses, allowable promotion, and eligibility for Medicaid reimbursement are areas of substantial interest to the federal government. AstraZeneca does not contend that states have no role or ability to seek recovery for fraud or Medicaid overpayments. However, the federal interest in having a federal forum in which to make consistent legal determinations of claims (be they federal or state) that require resolution of issues such as the appropriate FDA approval and regulation of drugs, the promotion of drugs by manufacturers, and reimbursement eligibility determinations under federal Medicaid law, far outweigh any state interest in adjudicating such matters in a state forum. In *Grable*, the Supreme Court noted that federal question jurisdiction is appropriate in cases where there is a federal interest in "claiming the advantages thought to be inherent in a federal forum." *Grable*,

545 U.S. at 313. The Court held that, in that case, "[t]he meaning of a federal tax provision is an important issue of federal law that sensibly belongs in federal court." *Id.* at 315. Likewise, the meaning and interpretation of the FDCA, the Medicaid statute, and related federal regulations are important issues that sensibly belong in federal court. *Id.*

22. ***Fourth***, there is a strong interest in having a federal court decide the federal questions raised by the Petition. The federal interest in uniform interpretation of the "intricate federal regulatory scheme including detailed" and substantial "federal funding provisions" is significant. *See In re Zyprexa Prods. Liab. Litig.*, Nos. 04-MD-1596, 07-CV-1933, 2008 WL 398378, at *6 (E.D.N.Y. Feb. 12, 2008) ("*Montana v. Eli Lilly*"). A comparison of the relative complexity of the federal and state laws that would be applied in connection with the plaintiffs' claims heavily weighs in favor of a federal forum. In construing similar state law claims, courts have stated that the TMFPA is "analogous" to the FCA and application of FCA interpretation is appropriate. *See U.S. ex rel. Williams v. McKesson Corp.*, 2014 WL 3353247, at *4 (N.D. Tex. July 9, 2014) (acknowledging the TMFPA's "analogous state law provisions" to the FCA and evaluating both Federal and Texas claims using "the FCA's well-defined legal requirements). In contrast, a state court handling plaintiffs' claims would be required to interpret and apply a complex federal regulatory scheme. Accordingly, there is a benefit to the "consistency of [a federal] forum." *Grable*, 545 U.S. at 319.

**OTHER REMOVAL/REMAND DECISIONS**

23. Cases involving substantially similar claims have already been removed to federal court. For example, several states brought separate actions in their home states against Eli Lilly raising state law claims based on allegations of off-label marketing of Zyprexa, which similarly turned on the interpretation of the FDCA and

associated federal regulations. Eli Lilly successfully removed the cases to federal court and joined them in multi-district litigation in the Eastern District of New York. *See, e.g.*, *Foti ex rel. Louisiana v. Eli Lilly*, 375 F. Supp. 2d 170, 172 (E.D.N.Y. 2005) (finding federal question jurisdiction); *McGraw ex rel. West Virginia v. Eli Lilly & Co.*, 476 F. Supp. 2d 230, 231 (E.D.N.Y. 2007) (same); *Hood ex rel. Mississippi v. Eli Lilly*, No. 07-645, 2007 WL 1601482, at *1 (E.D.N.Y. June 5, 2007) (same).

24. Likewise, in *Foti ex rel. Louisiana v. Merck & Co.*, the Attorney General of Louisiana brought state law claims related to Merck's alleged off-label marketing of the drug Vioxx. (Civ. No. 2005-9085 (E.D. La.).) Merck, relying on *Grable* and the Zyprexa cases cited above, successfully removed the case to federal district court. The case was subsequently transferred to a MDL with other similar cases. *See In re Vioxx*, MDL, No. 1657 (E.D. La.).

25. Further, in *West Virginia ex rel. McGraw v. Eli Lilly & Co.*, 476 F. Supp. 2d 230, 233 (E.D.N.Y. 2007), West Virginia's suit claiming injuries arising from payments for drugs made as part of its participation in the federal Medicaid program—the parameters and requirements of which are governed by federal law—was held to present a substantial and disputed federal question, and remand was denied.

26. The State may argue that *State of Texas ex rel. Ven-A-Care of Florida Keys, Inc. v. Abbott Labs. Inc.*, A-05-CA-897-LY, 2005 WL 5430194, at *3 (W.D. Tex. Dec. 5, 2005) ("*Ven-A-Care*") and *Texas v. Merck & Co., Inc.*, 385 F. Supp. 2d 604 (W.D. Tex. 2005)("*Merck*"), support remand. However, those cases are easily distinguishable from the instant case.

27. *Ven-A-Care*, unlike the allegations here, involved drug pricing claims. This Court remanded because it found that plaintiffs' state court claims were not premised on a disputed federal issue because the disputed term raised by the defendants, "Medicare Average Wholesale Price," was not defined by any federal statute or regulation. *Ven-A-Care*, 2005 WL 5430194, at *3. Here, however, the resolution of plaintiffs' claims turn on disputed federal questions, including whether Seroquel was "misbranded" under federal law and the interpretation of reimbursement of "medically necessary" prescriptions. Plaintiffs simply cannot prove their claims without demonstrating that AstraZeneca marketed Seroquel in a manner inconsistent with FDA approved indications and labeling—both of which are contested questions of federal law.

28. This case is similarly distinguishable from *Merck*, where the plaintiffs' claims arose solely from the defendant's alleged misrepresentations to the State, and where the plaintiffs did not accuse the defendant of violating a single federal law. 385 F. Supp. 2d at 608. Here, unlike in *Merck*, plaintiffs have expressly asserted that AstraZeneca violated federal law. Indeed, as alleged in the Petition, a violation of the FDCA is a necessary element of five out of six of plaintiffs' claims. Plaintiffs' theory is, in part, that AstraZeneca illegally promoted Seroquel for non-FDA approved uses. This promotion, in turn, caused the drugs to be "misbranded," in violation of the FDCA. *See, e.g.*, Pet. ¶¶ 76, 77, 84, 94, 106, 118. Further, as a result of this violation of federal law, the certifications that AstraZeneca was required to provide to Texas Medicaid were rendered false, such that all reimbursement of Seroquel by Texas was unlawful. *See, e.g.*, Pet. ¶ 2.

29. Further, in *Merck* the court did not have reason to consider the substantial and disputed federal questions raised by reimbursement for prescription drugs under the Federal Medicaid statute. Here, plaintiffs' request for reimbursement for all Seroquel prescriptions, *see* Pet. ¶ 160, necessarily requires interpretation and application of a complex federal regulatory scheme.

30. In sum, the fundamental allegations in the Petition—that AstraZeneca made false statements regarding the safety, efficacy, and FDA-approved indications for Seroquel and thus promoted "misbranded" products which were then reimbursed by Texas Medicaid under false pretenses—require the resolution of whether these products were misbranded under federal law and, even if they were, whether plaintiffs' theory is correct that these products were not eligible for reimbursement under the federal Medicaid statute as a result. These are uniquely federal questions that must be analyzed through the application of a uniquely federal regulatory regime.

**CONCLUSION**

31. For the reasons set forth above, this Court has jurisdiction over this matter based on federal question jurisdiction pursuant to 28 U.S.C. § 1331. To the extent that the foregoing bases for federal jurisdiction do not extend to one or more of the State's claims, this Court has supplemental jurisdiction over such claim or claims pursuant to 28 U.S.C. § 1367. This matter may be removed without regard to the citizenship or residence of the parties, in accordance with 28 U.S.C. § 1441(b) and (c).

32. This Notice is timely, as it was filed within thirty days after receipt by each Defendant of the notice from which each first ascertained that the case was one which was removable.

33. The United States District Court for the Western District of Texas is the federal judicial district encompassing the District Court for Travis County, Texas, where this suit was originally filed. Venue, therefore, is proper in this district under 28 U.S.C. § 1441(a).

34. Accordingly, the present lawsuit may be removed from the District Court for Travis County, Texas to the Austin Division of the United States District Court for the Western District of Texas pursuant to 28 U.S.C. §§ 1331 and 1441(a).

35. All of the defendants properly served in this action are a party to this notice.

WHEREFORE, notice is hereby given that this action is removed from the District Court for Travis County, Texas to the United States District Court for the Western District of Texas.

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

I HEREBY CERTIFY that on December 17, 2014, a copy of the NOTICE of REMOVAL was filed electronically with the Clerk of Court using the CM/ECF system. Notice of this filing will be sent to all counsel of record by United States mail, properly addressed and postage prepaid, this 17th day of December, 2014.

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